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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/724,274 | 11/26/2003 | Vanitha Ramakrishnan | 05882.0178.NPUS01 | 1255 |

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| EXAMINER | |
|---|---|
| HUMPHREY, DAVID HAROLD | |
| **ART UNIT** | **PAPER NUMBER** |
| 1643 | |

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/724,274 | RAMAKRISHNAN ET AL. | |
| | Examiner | Art Unit | |
| | David Humphrey | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 September 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *51-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *51-78* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restrictions***

1. Claims 1-50 are canceled in Applicants' amendment to the claims received on 9/13/2005.

Claims 51-78 are pending.

Claims 51-78 are subject to an election/restriction requirement.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 51-63, drawn to a chimeric or humanized anti-$\alpha 5\beta 1$ integrin antibody, classified in class 435, subclass 344.1.

II. Claims 64-72, drawn to a method for treating an ocular disease comprising administering an effective amount of anti-$\alpha 5\beta 1$ integrin antibody, classified in class 424, subclass 130.1.

III. Claim 73, drawn to a nucleic acid encoding a polypeptide, classified in class 536, subclass 23.1.

IV. Claim 74-78, drawn to a vector and a host cell, classified in class 435, subclass 320.1.

3. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons. Groups I, III, and IV, are directed to

products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the antibodies of Group I have have substantially different physical, chemical, structural and functional properties from the nucleic acids of Group III and the vectors of Group IV. Moreover, they are made using different techniques and reagents and have materially different modes of operation in vivo. And while some of the nucleic acids of Group III encode for the heavy and light chains of the antibodies of Group I, DNA, deoxyribonucleic acids are unbranched polymers composed of four subunits whereas the polypeptides encoding the light and heavy chains of Group I are a linear order of amino acid residues. Moreover, they are made using different techniques and reagents and have materially different modes of operation in vivo.

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Group I can also be used purify the antigen.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. If either Group I or Group II is elected, further restriction is required. Applicants must further elect a heavy chain variable region from the group:

a. SEQ ID NO: 1;

b. SEQ ID NO: 16;

c. SEQ ID NO: 20;

d. SEQ ID NO: 25;

e. SEQ ID NO: 28; and

f. SEQ ID NO: 31.

**AND** a light chain variable region from the group:

g. SEQ ID NO: 7;

h. SEQ ID NO: 18;

i. SEQ ID NO: 22;

j. SEQ ID NO: 26; and

k. SEQ ID NO: 32.

The heavy chain variable regions listed above as a.— f. and the light chain variable regions listed above as g.—k. are patentably distinct from each other and together comprise patentably distinct antibodies. The amino acid sequences listed above are separate and distinct. In order to be fully responsive, if Applicant elects Group I or Group II, Applicant must further elect one heavy chain variable region AND one light chain variable region. Applicant is advised that the election of the SEQ IDs in 4A above is not a species election requirement; rather this is a restriction requirement.

5. If Group III is elected, further restriction is required. Applicants' must further elect a nucleic acid encoding a polypeptide comprising an amino acid sequence selected from the group:

aa. SEQ ID NO: 2;

ab. SEQ ID NO: 3;

ac. SEQ ID NO: 4;

ad. SEQ ID NO: 5;

ae. SEQ ID NO: 6;

af. SEQ ID NO: 8;

ag. SEQ ID NO: 9;

ah. SEQ ID NO: 10;

ai. SEQ ID NO: 11;

aj. SEQ ID NO: 12;

ak. SEQ ID NO: 16;

al. SEQ ID NO: 18;

am. SEQ ID NO: 20;

an. SEQ ID NO: 22;

ao. SEQ ID NO: 25;

ap. SEQ ID NO: 26;

aq. SEQ ID NO: 28;

ar. SEQ ID NO: 26;

as. SEQ ID NO: 28;

at. SEQ ID NO: 31; and

au. SEQ ID NO: 32.

The nucleic acids listed above as aa.— au. are patentably distinct from each other. The amino acid sequences encoded by the nucleic acids listed above are separate and distinct. In order to be fully responsive, if Applicant elects Group III, Applicant must further elect one a nucleic acid from aa.—au. Applicant is advised that the election of a SEQ ID in 5 above is not a species election requirement; rather this is a restriction requirement.

6. If Group IV is elected, further restriction is required. Applicants' must further elect a vector comprising a nucleic acid sequence selected from the group:

ba. SEQ ID NO: 15;

bb. SEQ ID NO: 17;

bc. SEQ ID NO: 19;

bd. SEQ ID NO: 21;

be. SEQ ID NO: 23;

bf. SEQ ID NO: 24;

bg. SEQ ID NO: 27;

bh. SEQ ID NO: 29; and

bi. SEQ ID NO: 30.

The nucleic acid sequences of the vectors listed above as ba.— bi. are patentably distinct from each other. The nucleic acids listed above are separate and distinct. In order to be fully responsive, if Applicant elects Group IV, Applicant must further elect one a vector nucleic acid sequence from ba.—bi. Applicant is advised that the election of a SEQ ID in 6 above is not a species election requirement; rather this is a restriction requirement.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

April 3, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT E[illegible]